General

Guideline Title

Guideline for management of wounds in patients with lower-extremity arterial disease.

Bibliographic Source(s)

Wound, Ostomy and Continence Nurses Society (WOCN). Guideline for management of wounds in patients with lower-extremity arterial disease. Mount Laurel (NJ): Wound, Ostomy and Continence Nurses Society (WOCN); 2014. 204 p. (WOCN clinical practice guideline series; no. 1). [625 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Bonham PA, Flemister BG. Guideline for management of wounds in patients with lower-extremity arterial disease. Mount Laurel (NJ): Wound, Ostomy and Continence Nurses Society (WOCN); 2008. 63 p. (WOCN clinical practice guideline series; no. 1). [268 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The level of evidence ratings (A-C) and the classifications of the strength of the recommendations (I, II, III, IV) are defined at the end of the "Major Recommendations" field. Where a level-of-evidence was not provided, there is a designation to indicate the recommendation was based on the consensus of opinion of the task force (Task Force Consensus [TFC]).

A. Assessment
    1. Prior to treatment, assess causative and contributive factors and significant signs and symptoms to differentiate types of lower-extremity wounds, which require varying treatments (see the Algorithm: Differential Assessment of Wounds, Appendix A in the original guideline document). *(TFC)*
    2. Review health history to identify risk factors for lower-extremity arterial disease (LEAD) (e.g., tobacco use, diabetes, hypertension, dyslipidemia, renal insufficiency, etc.), wound history, pain history, history of prescribed/self-prescribed medications, and coexisting diseases and comorbidities. *(TFC)*
        a. Assess pain characteristics: Onset, duration, location, precipitating and alleviating factors, and presence or absence of intermittent claudication. *(TFC)*
        b. Differentiate acute limb ischemia (i.e., rapid, sudden decrease in limb perfusion often associated with thrombosis) from critical

limb ischemia (CLI) that is chronic and progressive in nature due to atherosclerosis. *Level of evidence = C (Class I)*

3. Review pertinent labs to identify risk markers for LEAD:
    a. Elevated low-density lipoprotein (LDL) cholesterol, total cholesterol and triglycerides; reduced high-density lipoprotein (HDL) cholesterol. *Level of evidence = B (Class I)*
    b. Elevated homocysteine. *Level of evidence = B (Class II)*
4. Assess the wound:
    a. Determine wound characteristics: Location, pain, shape, size, color of wound base and type tissue, wound edges, periwound skin, exudate, and presence/absence of odor or necrosis. *(TFC)*
    b. Assess for wound complications: Infection, cellulitis, gangrene or osteomyelitis. *(TFC)*
5. Conduct a comprehensive, bilateral lower-extremity examination:
    a. Assess functional ability and physical activity. *(TFC)*
    b. Assess the lower extremities for ischemic skin changes: Purpura, atrophy of the skin, subcutaneous tissue and muscle; shiny and taut skin, hair loss and/or dystrophic nails. *(TFC)*
    c. Perform a vascular assessment (e.g., pedal pulses, ankle brachial index [ABI]) on any individual that presents with a pressure ulcer on the lower limb/foot/heel. *Level of evidence = C (Class I)*
    d. Determine perfusion status by assessing skin temperature, capillary refill, venous refill, color changes and paresthesias. *(TFC)*
    e. Determine presence or absence of pedal pulses. Palpate both dorsalis pedis and posterior tibial pulses of each lower extremity. Presence of palpable pulses does not rule out LEAD. *Level of evidence = B (Class I)*
    f. Auscultate femoral/popliteal arteries for bruits. *Level of evidence = C (Class II)*
    g. Observe for signs of neuropathy (e.g., decreased sensation, weakness of ankles or feet, gait abnormalities, foot drop/drag), which can cause impaired muscle function. *Level of evidence = B (Class I)*
    h. Determine neurosensory status by screening both feet for loss of protective sensation with a monofilament, tuning fork and percussion hammer. *(TFC)*
    i. Measure the ABI using a Doppler and sphygmomanometer to assess arterial blood flow in both lower extremities and determine the level of ischemia. *Level of evidence = B (Class I)*
    j. Calculate ABI for each leg using the higher of the ankle pressures (dorsalis pedis or posterior tibial) divided by the higher of the brachial pressures from the right or left arm. *Level of evidence = C (Class I)*
    k. Interpret the ABI taking into consideration the overall results of the clinical exam:
        - Normal: ABI greater than or equal to 1.00; LEAD: ABI less than or equal to 0.90; borderline perfusion: ABI less than or equal to 0.60 to 0.80; severe ischemia: ABI less than or equal to 0.50; and critical ischemia: ABI less than or equal to 0.40.
        - The ABI can be elevated (>1.30) in individuals with diabetes, renal failure or arthritis due to calcification of the ankle arteries, which can also cause noncompressible arteries (i.e., unable to obliterate the pulse signal at a cuff pressure >250 mmHg).

        Level of evidence = C (Class II)

    l. Recheck the ABI periodically (every 3 months) for patients with nonhealing, lower-extremity wounds. *Level of evidence = C (Class II)*
    m. Refer patients who have symptoms of LEAD but a normal, resting ABI to a vascular laboratory for an exercise ABI test, or other testing. *Level of evidence = C (Class I)*
    n. Measure toe pressures with photoplethysmography/determine a toe brachial index (TBI) if the ABI is greater than 1.30, unmeasurable, or the vessels are non-compressible.
        - TBI less than 0.64 indicates LEAD. *Level of evidence = B (Class II)*
        - A systolic toe pressure less than 30 mmHg or less than 50 mmHg in persons with diabetes indicates CLI. *Level of evidence = C (Class II)*
    o. Assess tissue perfusion with transcutaneous oxygen measurement (TcPO2) if a wound is not healing and the ABI is less than 0.90, toe pressure is less than 30 mmHg, or if unable to perform an ABI or toe pressure/TBI because of noncompressible ankle arteries or an amputation. A TcPO2 less than 40 mmHg is considered hypoxic and is associated with impaired wound healing. *Level of evidence = A (Class I)*
    p. Consider noninvasive tests if the ABI, toe pressure, TBI or TcPO2 are inconclusive or cannot be performed; or if the ABI is greater than 1.30:
        - Duplex ultrasound. *Level of evidence = B (Class II)*
        - Pulse volume recordings. *Level of evidence = C (Class II)*
        - Skin perfusion pressures. *Level of evidence = C (Class II)*
    q. Consider additional noninvasive tests to select surgical or endovascular candidates:

- Magnetic resonance angiography. *Level of evidence = A (Class II)*
- Computed tomographic angiography. *Level of evidence = B (Class II)*
- Multidetector computed tomographic angiography. *Level of evidence = A (Class II)*

r. Consider use of invasive studies such as contrast catheter angiography to definitively determine the anatomic location of LEAD when surgery is planned. *Level of evidence = B (Class II)*

s. Assess all patients with ischemic rest pain or pedal wounds for indicators of CLI (ankle pressure <50 mmHg; toe pressure <30 mmHg [<50 mmHg if diabetes]; TcPO2 <30 mmHg). *Level of evidence = C (Class I)*

6. Assess for symptoms of depression. *Level of evidence = C (Class I)*

B. Referral for Further Evaluation

1. Refer patients with the following symptoms, conditions or assessment findings for further vascular or surgical evaluation, and/or biopsy or culture:
   - Atypical wounds
   - Clinical signs of infection or cellulitis; suspected osteomyelitis
   - Intractable pain
   - Wounds and/or edema in mixed arterial/venous disease that fail to respond to compression therapy or worsens
   - Absence of both pedal and posterior tibial pulses
   - An ABI less than 0.90 plus any one of the following—wounds failing to improve within 2 to 4 weeks of appropriate therapy, severe ischemic pain, and/or intermittent claudication
   - Toe pressure less than 30 mmHg (<50 mmHg if diabetes)
   - Ankle pressure less than 50 mmHg
   - ABI less than 0.50
   - ABI greater than 1.30 or noncompressible vessels and unable to obliterate pulse signal at cuff pressures greater than 250 mmHg.

   Level of evidence = C (Class I)

2. Make an urgent vascular and/or surgical referral for patients with symptoms of acute limb ischemia, an ABI less than 0.40, and/or gangrene. (TFC)

C. Interventions

1. Recommend patients with wounds and LEAD seek care guided by a wound care expert. *Level of evidence = C (Class I)*
2. Relate wound treatments to adequacy of perfusion status. *Level of evidence = C (Class I)*
3. Cleanse wounds with noncytotoxic cleansers. *Level of evidence = C (Class II)*
4. Offload heels of bed/chairbound patients with wounds and/or are at risk for pressure wounds with products specifically designed to eliminate/redistribute heel pressure. *Level of evidence = C (Class I)*
5. Maintain dry, stable eschar/blisters in noninfected ischemic wounds. *Level of evidence = C (Class I)*

Debridement

6. Do not debride wounds with stable, black eschars until perfusion status is determined: Debridement may be contraindicated. *Level of evidence = C (Class IV)*
7. Consider revascularization and surgical removal of necrotic tissue from an infected wound on an ischemic leg, which is the treatment of choice for limb salvage. *Level of evidence = C (Class I)*
8. Closely monitor autolytic or enzymatic debridement if used for open, draining ischemic wounds with necrotic tissue. *(TFC)*

Dressings

9. Choose dressings for ischemic wounds that permit frequent visualization and inspection of the wound. *(TFC)*
10. Conduct a carefully monitored trial of moist dressings for ischemic open and draining wounds with soft slough/necrotic material or exposed bones or tendons. *Level of evidence = C (Class II)*

Infection

11. Monitor ischemic wounds closely for signs/symptoms of infection, which can be subtle because of reduced blood flow. *Level of evidence = C (Class I)*
12. Use tissue biopsy, considered the gold standard, to confirm a diagnosis of infection. Limited studies (not specific to LEAD) have demonstrated that noninvasive, quantitative swab cultures using the Levine technique are a reasonable alternative to biopsies in general clinical practice settings. *Level of evidence = C (Class II)*
13. Refer patients with infected, ischemic wounds, which are limb threatening, for immediate evaluation, culture-guided antibiotic therapy, assessment of perfusion status, and/or need for surgical intervention. *Level of evidence = C (Class I)*

Antibiotics

14. Consider topical antibiotic dressings for a limited time (e.g., 2 weeks) if critical colonization is suspected. *Level of evidence = C (Class II)*
15. Do not rely solely on topical antibiotics to treat infected, ischemic wounds. *Level of evidence = C (Class IV)*
16. Promptly institute culture-guided, systemic antibiotics for patients with LEAD or CLI and evidence of limb/wound infection or cellulitis. *Level of evidence = C (Class II)*

Nutrition

17. Refer patients with LEAD/CLI for nutritional counseling to identify nutritional and vitamin deficiencies that warrant intervention. *Level of evidence = C (Class II)*
18. Consider the Mediterranean diet, which has been associated with reduced incidence of LEAD. *Level of evidence = B (Class II)*

Pain Management

19. Institute a regular exercise program for medically stable patients with intermittent claudication. Supervised exercise sessions, 3 times per week, of 30 to 60 minutes of treadmill or track walking to the point of pain, followed by rest, promotes increased pain-free walking and total walking distances. *Level of evidence = A (Class I)*
20. Recommend self-directed walking programs for those who are unwilling or unable to participate in supervised exercise programs. *Level of evidence = A (Class I)*
21. Consider the need for analgesia for patients with persistent pain, and/or premedication prior to wound care. Refer patients with severe and intractable pain for an evaluation for surgical reconstruction. *(TFC)*
22. Consider the following pain management strategies for patients with intractable pain and CLI who are unsuitable for surgical reconstruction:
    - Spinal cord stimulation for patients whose foot TcPO2 is between 10 to 30 mmHg, and increases more than 10 mmHg during a trial of spinal cord stimulation. *Level of evidence = A (Class II)*
    - Lumbar sympathectomy. *Level of evidence = C (Class II)*
    - Peridural anesthesia. *Level of evidence = C (Class II)*

Compression Issues/Management of Edema in Patients with Mixed Arterial/Venous Disease

23. Use a reduced level of compression (23 to 30 mmHg at the ankle) for patients with LEAD, venous disease, wounds, and edema (ABI >0.50 to <0.80); and closely supervise the patient for complications. *Level of evidence = C (Class II)*
24. Avoid compression if ABI is less than 0.50; ankle pressure is less than 70 mmHg, or toe pressure is less than 50 mmHg. *Level of evidence = C (Class IV)*
    - If the patient is revascularized, consider compression to manage the edema due to the venous disease. *Level of evidence = C (Class II)*
25. Carefully monitor patients with neuropathy if compression is provided because they may not sense pain or discomfort from compression that is too tight. *(TFC)*
26. Consider use of graduated, compression stockings (18 to 30 mmHg) to manage postoperative edema after lower-extremity, bypass surgery. *Level of evidence = B (Class III)*
27. If LEAD is present (ABI ≤0.90), prior to the use of antiembolism compression stockings (AECS) or mechanical devices, consult with the primary healthcare provider to determine if AECS/mechanical devices are indicated and safe, or if other interventions are warranted. *Level of evidence = C (Class I)*

Medications

28. Recommend statin therapy for lipid control, to reduce cardiovascular mortality and morbidity. *Level of evidence = A (Class I)*
29. Recommend antiplatelet therapy (e.g., aspirin, clopidogrel, dipyridamole) for patients with symptomatic LEAD to decrease mortality and cardiovascular events. *Level of evidence = A (Class I)*
    - Cilostazol (100 mg oral 2 times per day) increases HDL cholesterol, decreases triglycerides and LDL cholesterol, and improves the walking distances of patients with intermittent claudication. *Level of evidence = A (Class I)*
    - Aspirin (75 to 325 mg oral per day) has been recommended as a safe and cost effective option for symptomatic patients:
        - Improves walking speed. *Level of evidence = C (Class II)*
        - Decreases vascular events. *Level of evidence = B (Class III)*
        - Decreases strokes. *Level of evidence = A (Class I)*
30. Consider clopidogrel (75 mg oral per day) as an alternative to aspirin to reduce the risk of stroke, myocardial infarction, or vascular deaths in patients with symptomatic LEAD or CLI. *Level of evidence = B (Class II)*
31. Consider a trial of prostanoids, which have shown some benefit in pain relief and wound healing for patients with CLI. *Level of evidence = A (Class II)*

32. Consider a trial of pentoxifylline as a second-line therapy for patients with intermittent claudication. *Level of evidence = A (Class II)*
33. Consider angiotensin-converting enzyme inhibitors (e.g., Ramipril 10 mg oral per day) to reduce cardiovascular risks and improve pain-free walking time in patients with claudication. *Level of evidence = A (Class II)*

Surgical Options

34. Carefully assess risks versus short-term and long-term benefits of bypass surgery or angioplasty: Short-term surgical benefits may not be sustained long term. *Level of evidence = A (Class III)*
35. Consider antithrombotic agents to improve patency of vascular grafts. *Level of evidence = A (Class II)*
36. Assess TcPO2 levels prior to amputation. Successful healing after amputation has been associated with:
    - Preoperative TcPO2 levels greater than 20 mmHg. *Level of evidence = A (Class II)*
    - Increase in TcPO2 greater than 10 mmHg after an oxygen challenge. *Level of evidence = C (Class II)*
37. Consider the need for strict glycemic control for patients undergoing lower-extremity bypass surgery. *Level of evidence = C (Class II)*
38. Weigh the risks of anemia against the risk of transfusion if the hemoglobin level is 7.0 to 9.0 g/dL, taking into consideration other hemodynamic and physiological parameters. *Level of evidence = C (Class II)*
39. Consider prophylactic antibiotics:
    - Five-day course of combined antibiotics after major lower-limb amputation. *Level of evidence = C (Class II)*
    - Twenty-four hour course of broad-spectrum antibiotics for patients having revascularization with grafts. *Level of evidence = A (Class I)*
40. Consider the benefits of endovascular procedures over surgery for individuals who have a life expectancy of 2 years or less, or are 80 years of age and older. *Level of evidence = C (Class II)*

Consider Adjunctive Therapies

41. A trial of conservative therapy (e.g., topical therapy) for patients with wounds and borderline blood flow (i.e., ABI = 0.62; TcPO2 >30 mmHg; ankle pressure >70 mmHg) if they are free of limb-threatening sepsis. *Level of evidence = C (Class II)*
42. Low frequency ultrasound. *Level of evidence = B (Class II)*
43. Electrotherapy (high-voltage pulsed current) for patients with ischemic wounds. *Level of evidence = C (Class II)*
44. Hyperbaric oxygen therapy for patients with nonhealing, ischemic wounds (TcPO2 <40 mmHg). *Level of evidence = B (Class II)*
45. Arterial flow augmentation (intermittent pneumatic compression) for individuals who are not surgical candidates:
    - Intermittent claudication. *Level of evidence = B (Class II)*
    - Limb-threatening arterial disease. *Level of evidence = C (Class II)*
46. Topical negative pressure for wounds with infected vascular grafts. *Level of evidence = C (Class II)*
47. Bone marrow-derived, mononuclear cell therapy as an option for pain relief or limb salvage in patients who are not surgical candidates:
    - Intermittent claudication. *Level of evidence = B (Class II)*
    - CLI. *Level of evidence = A (Class II)*
48. Immune modulation therapy for patients with claudication or CLI. *Level of evidence = B (Class II)*

D. Patient Education and Risk Reduction Strategies

1. Educate patients about risk reduction and chronic disease management (e.g., control diabetes, hypertension, cholesterol, and weight; adhere to medication regimen), and wound care procedures for patients with wounds. *Level of evidence = C (Class I)*
2. Recommend tobacco cessation, which slows the progression of atherosclerosis, decreases the risk of cardiovascular events and death, and may decrease the overall risk of LEAD after long-term cessation. *Level of evidence = B (Class I)*
    - Assist in developing a plan for tobacco cessation, which includes behavioral and/or pharmacological interventions (nicotine replacement therapy (NRT); non-nicotinic therapy). *Level of evidence = B (Class I)*
    - Recommend preoperative tobacco cessation to reduce postoperative complications. *(TFC)*
    - Avoid secondhand smoke. *Level of evidence = C (Class II)*
3. Teach measures to:
    - Promote blood flow, maintain intact skin, and prevent trauma: Avoid leg elevation and use a dependent position for legs; avoid chemical, thermal and mechanical trauma; examine limbs/feet daily for blisters, wounds, signs of infection; precautions to observe/report if compression is used to manage edema in mixed arterial/venous disease; have routine nail and foot care provided by a professional; and visit a health care provider on a regular basis. *(TFC)*
    - Protect feet, toes and heels: Wear proper-fitting shoes/footwear with socks or hose; use pressure redistribution surfaces, products, or devices to protect toes and other bony prominences; and offload the heels if bedbound or chairbound. *Level of evidence = C (Class I)*
4. Increase regular exercise and physical activity to improve symptoms of claudication. *Level of evidence = A (Class I)*

5. Encourage tobacco users to exercise: Some negative effects of tobacco use may be minimized by 8 hours of exercise per week. *(TFC)*
6. Drink in moderation if already consuming alcohol. *Level of evidence = B (Class II)*

Definitions

Level-of-Evidence Rating for Guideline Recommendations

Level of Evidence A	Level of Evidence B	Level of Evidence C	Task Force Consensus (TFC)
Two or more supporting randomized controlled trials (RCTs) of at least 10 humans with lower-extremity arterial disease (LEAD) (at Levels I or II), a meta-analysis of RCTs or a Cochrane Systematic Review of RCTs.	One or more supporting controlled trials of at least 10 humans with LEAD, or two or more supporting non-randomized trials of at least 10 humans with LEAD (at Level III).	Other studies not meeting Level B criteria, two or more supporting case series of at least 10 humans with LEAD, or expert opinion.	Where a level-of-evidence is not included, the information represents a consensus of the task force members.

Classification of Recommendations: Potential Benefit/Effectiveness versus Harm

Class I	Class II	Class III	Class IV
There is evidence and/or agreement of expert opinion that a procedure or treatment is beneficial and effective with greater benefit than harm. Is indicated and recommended; should be done.	There is limited evidence and/or agreement of expert opinion that a procedure or treatment can be beneficial and effective with greater benefit than harm. May be indicated; is reasonable to perform; may be considered.	Evidence and/or agreement of expert opinion about a procedure or treatment is less well established or uncertain and has conflicting evidence or divergence of opinion about the benefit and effectiveness; or there are risks/side effects that may limit benefit. May be reasonable; may be considered in select instances.	There is evidence and/or agreement of expert opinion that a procedure or treatment is not beneficial or effective, and/or can be harmful in some cases where risks/side effects outweigh benefit. Is not indicated or recommended; should not be performed.

Clinical Algorithm(s)

The following algorithms are provided in the original guideline document:

- Appendix A – Algorithm: Differential Assessment of Wounds
- Appendix C – Algorithm for Tobacco Cessation: The 5 As and 5 Rs

Scope

Disease/Condition(s)

- Lower-extremity arterial disease (LEAD)
- Lower-extremity wounds and ulcers

Guideline Category

Diagnosis

Evaluation

Management

Risk Assessment

Screening

Treatment

Clinical Specialty

Cardiology

Dermatology

Endocrinology

Family Practice

Internal Medicine

Nursing

Orthopedic Surgery

Physical Medicine and Rehabilitation

Podiatry

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Health Care Providers

Nurses

Physical Therapists

Physician Assistants

Physicians

Podiatrists

Guideline Objective(s)

To support clinical practice by providing consistent, research-based information with the goal of improved, cost-effective patient outcomes as well as to stimulate increased wound research

Target Population

Patients with lower-extremity arterial disease (LEAD) and lower-extremity wounds

Interventions and Practices Considered

Evaluation/Diagnosis

1. Assessment of causative and contributing factors along with significant signs and symptoms
2. Review of health history to identify risk factors
3. Review of labs to identify risk markers
4. Assessment of the wound
5. Conducting a comprehensive, bilateral lower-extremity examination
6. Assessment for symptoms of depression
7. Referral for further evaluation (vascular or surgical evaluation, and/or biopsy or culture)

Treatment/Management

1. Referral to wound care expert
2. Cleansing of wounds with cytotoxic cleansers
3. Offload heels of bed/chairbound patients
4. Debridement and dressing
5. Infection monitoring, diagnosis and treatment
6. Topical and systemic antibiotics
7. Consideration of nutritional/vitamin deficiencies
8. Pain management
9. Compression issues/management of edema
10. Medications
    - Statin therapy
    - Antiplatelet therapy (e.g., cilostazol, aspirin)
    - Clopidogrel
    - Prostanoids
    - Pentoxifylline
    - Angiotensin-converting enzyme inhibitors
11. Consideration of surgical options (bypass surgery, angioplasty)
12. Consideration of adjunctive therapies
    - Conservative topical therapy
    - Ultrasound
    - Electrotherapy
    - Hyperbaric oxygen therapy
    - Arterial flow augmentation
    - Topical negative pressure
    - Bone marrow-derived mononuclear cell therapy
    - Immune modulation therapy
13. Use of patient education and risk reduction strategies

Major Outcomes Considered

- Wound healing
- Complications of lower-extremity arterial disease (LEAD)
- Quality of life
- Limb loss
- Mortality rates
- Accuracy/limitations of screening/diagnostic tests

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Review Process

The primary authors of this guideline independently conducted searches of MEDLINE, CINAHL and Cochrane Library databases for studies published in English from January 2008 through June 2013. The following medical subject headings (MeSH) were used to search for each specific question related to lower-extremity arterial disease (LEAD)—arterial disease, arterial insufficiency, peripheral arterial disease, peripheral vascular disease, lower-extremity arterial disease, peripheral arterial occlusive disease, lower-extremity ischemic wounds and ulcers, and critical limb ischemia (CLI).

The search targeted randomized controlled trials (RCTs), prospective clinical trials and retrospective studies with at least 10 subjects, meta-analyses, and systematic reviews. If available and relevant, national guidelines and published expert opinion were included to support expert opinion in areas that were clinically important where research was lacking or non-existent. Titles of references and abstracts were retrieved from the electronic searches and were screened for relevance to LEAD and the search questions, and in accordance with the inclusion and exclusion criteria. After the initial screening, full-text articles were obtained that met inclusion criteria. Additionally, some relevant studies were included that were identified from reference lists of selected articles.

Inclusion Criteria

- Published in English; peer reviewed literature
- Available abstract
- Primary focus on LEAD or reported specific data relevant to LEAD
- 10 subjects included in studies/case studies
- Human studies
- Primary research reports relevant to LEAD and the search questions

Exclusion Criteria

- Foreign language publication
- Abstract not available
- Secondary reports of research
- Conference abstracts/posters
- Primary focus not on LEAD or lacked specific data about LEAD
- Non-human studies
- Description of study or outcomes lacked sufficient detail to draw conclusions

Number of Source Documents

- 381 full-text articles were reviewed
- 66 articles were excluded

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Rating of Research Evidence

Level I: A randomized controlled trial (RCT) demonstrating a statistically significant difference in at least one important outcome defined by $p < .05$. Level I trials can conclude the difference is not statistically significant if the sample size is adequate to exclude a 25% difference among study arms with 80% power.

Level II: An RCT not meeting Level I criteria.

Level III: A nonrandomized controlled trial with contemporaneous controls selected by some systematic method. A control might have been selected due to its perceived suitability as a treatment option for an individual patient.

Level IV: A before-and-after study or a case series of at least 10 patients using historical controls or controls drawn from other studies.

Level V: A case series of at least 10 patients with no controls.

Level VI: A case report of fewer than 10 patients.

Level-of-Evidence Rating for Guideline Recommendations

Level of Evidence A	Level of Evidence B	Level of Evidence C	Task Force Consensus (TFC)
Two or more supporting randomized controlled trials (RCTs) of at least 10 humans with lower-extremity arterial disease (LEAD) (at Levels I or II), a meta-analysis of RCTs or a Cochrane Systematic Review of RCTs.	One or more supporting controlled trials of at least 10 humans with LEAD, or two or more supporting non-randomized trials of at least 10 humans with LEAD (at Level III).	Other studies not meeting Level B criteria, two or more supporting case series of at least 10 humans with LEAD, or expert opinion.	Where a level-of-evidence is not included, the information represents a consensus of the task force members.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

From the selected, full-text articles, the primary authors extracted the following data: Source/citation (author, publication date, title, publication); type/design of study; methods (sample size, setting/location, description of subjects, interventions, tests/measures); results/findings including statistical significance of findings (p values, odds ratios, hazard ratios, confidence intervals, sensitivity/specificity, etc. as appropriate to the study); and conclusions. For studies of diagnostic or screening tests, data included if a valid reference standard was used. For systematic reviews/meta-analyses, data included number/quality of randomized controlled trials (RCTs) reviewed, findings, and conclusions.

For each article, a narrative summary of the extracted data was prepared and reviewed by the primary authors and the final recommendations were based on the review of evidence by the task force. Based on judgment of the authors, studies were assessed as acceptable or unacceptable for inclusion and excluded if there were methodological issues or insufficient detail to evaluate the results. Additionally, the primary authors rated the research (Level I to Level VI) using criteria as identified in the preface of the original guideline document (Sackett, 1989; Cook, Guyatt, Laupacis, & Sackett, 1992). Any differences of opinion about the quality/rating of the studies for inclusion in the guideline were resolved by discussion between the primary authors or by consensus after a review and discussion by the full task force.

Synthesis and Evaluation of Evidence

The two primary authors synthesized the data and prepared a descriptive, narrative summary of the available evidence derived from the search and review of the literature. The lower-extremity arterial disease (LEAD) guideline is organized into a topical outline format that addresses key content areas for assessment and management of patients with or at risk for wounds due to LEAD. The summary of evidence derived from the review and

evaluation of literature was integrated into the appropriate content sections of the guideline and a draft was presented to all task force members for review, discussion, clarification, and development of consensus. A series of conference calls was conducted during 2013 and 2014 and the task force reviewed/evaluated the evidence in the draft guideline until consensus was reached.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development

The Wound, Ostomy and Continence Nurses Society (WOCN) developed this evidence-based guideline using the following process: (a) A task force of nurses from the WOCN membership, representing a wide range of experience and clinical practice backgrounds, convened to plan the guideline format; (b) a topical outline was designed and specific questions about lower-extremity arterial disease (LEAD) were proposed to guide the search of the literature for evidence; and (c) studies reporting primary data relevant to LEAD and specific therapies or diagnostic modalities were included in the review.

The task force developed the following questions to guide the evidence-based review of the literature:

Screening and Diagnosis

1. What are the risk factors for LEAD?
2. What are reliable, noninvasive methods to diagnose LEAD (e.g., palpable pulses, vascular tests such as ankle brachial index [ABI], toe pressures/toe brachial index [TBI], transcutaneous oxygen measurement, segmental pressures)?
3. Who should have ABI screening?
4. What indicators should be used to determine whether perfusion status is adequate, borderline or ischemic?
5. What are the indicators of critical limb ischemia (CLI)?

Healing and Treatments

6. How does perfusion status affect the potential for wound healing and treatments for LEAD?
7. When is compression therapy indicated or contraindicated for patients with LEAD?

Infection

8. What is the most appropriate method to diagnose infected wounds in patients with LEAD (e.g., swabs, cultures, biopsies)?
9. Are topical and/or systemic antibiotics, effective treatments for infected, ischemic wounds?

Topical Wound Treatments

10. What topical dressings are most effective for treating lower-extremity wounds in patients with LEAD?
11. Are occlusive and/or moist dressings appropriate treatments for wounds due to LEAD?
12. What cleansing methods are appropriate for wounds due to LEAD?
13. Is debridement indicated or contraindicated for wounds due to LEAD? What debridement methods are most appropriate? When are they indicated or contraindicated?

Management of Patients with LEAD

14. What effect does smoking cessation have on wound healing in patients with LEAD?
15. Is exercise therapy an effective treatment for LEAD and claudication pain?
16. Are any medications effective in treating LEAD (e.g., cilostazol, pentoxifylline)?
17. What surgical interventions are the most effective therapies for patients with critical ischemia (e.g., angioplasty, bypass)?
18. Is hyperbaric oxygen therapy effective for wound healing in patients with LEAD or critical ischemia?
19. What adjunctive therapies are effective treatments for patients with LEAD or ischemic wounds?
20. What nutritional factors contribute to the development of LEAD and/or influence healing of ischemic wounds?
21. When should patients be referred for vascular/surgical evaluation?

22. What type of patient education is effective for patients with LEAD?

After the two primary authors reviewed the selected studies, the written summary of the evidence was presented to all task force members for review, discussion, clarification, and development of consensus. A series of conference calls was conducted during 2013, and the guideline was finalized incorporating evidence from the studies.

Development of Recommendations

Based on the evidence in the guideline, recommendations were developed for specific areas where evidence was sufficient to support the recommendation. In selected areas where evidence about clinically significant topics was lacking or nonexistent, the recommendations were based on the consensus of expert opinion by the task force.

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations: Potential Benefit/Effectiveness versus Harm

Class I	Class II	Class III	Class IV
There is evidence and/or agreement of expert opinion that a procedure or treatment is beneficial and effective with greater benefit than harm. Is indicated and recommended; should be done.	There is limited evidence and/or agreement of expert opinion that a procedure or treatment can be beneficial and effective with greater benefit than harm. May be indicated; is reasonable to perform; may be considered.	Evidence and/or agreement of expert opinion about a procedure or treatment is less well established or uncertain and has conflicting evidence or divergence of opinion about the benefit and effectiveness; or there are risks/side effects that may limit benefit. May be reasonable; may be considered in select instances.	There is evidence and/or agreement of expert opinion that a procedure or treatment is not beneficial or effective, and/or can be harmful in some cases where risks/side effects outweigh benefit. Is not indicated or recommended; should not be performed.

Cost Analysis

The guideline developers reviewed published studies with cost analyses.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

The completed guideline was peer reviewed by an independent group of six certified Wound, Ostomy and Continence nurses for relevance, clarity, accuracy, comprehensiveness/organization, consistency with current research/best practices, and usefulness to the target population. Feedback was reviewed by the task force and incorporated into the final document as appropriate.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field). References in support of the recommendations are identified in the full text of the original guideline document and in the final reference list.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Identification of patients with lower-extremity arterial disease (LEAD) who are at risk for developing wounds
- Identification of patients whose current wounds are caused or complicated by LEAD
- Implementation of appropriate strategies and plans may:
  - Reduce or eliminate known modifiable risk factors for LEAD
  - Attain/maintain intact skin
  - Reduce pain
  - Prevent complications
  - Promptly identify/manage complications
  - Optimize potential for wound healing
  - Promote limb preservation
  - Improve functional status of symptomatic patients
  - Involve patient/caregiver in self-management

Potential Harms

- The clinical usefulness of clopidogrel must be weighed against the side effects (risk of major bleeding) and high costs. There is a potential for rebound mechanism after stopping clopidogrel in patients who receive endovascular brachytherapy after stenting.
- Wounds treated with topical antibiotics may develop sensitivity and resistant organisms over time.
- Invasive arterial evaluation is associated with risks of bleeding, infection and contrast nephropathy.
- A 17% risk of complications was reported with spinal cord stimulation (SCS) (i.e., implantation problems, reintervention to change stimulation, and infection of the lead or pulse generator pocket).
- Adverse effects depended on the type of nicotine replacement therapy (NRT) product and included irritation of the skin from patches and mouth from the gum and tablets.
- The most common adverse events of magnetic resonance angiography (MRA) were paresthesia, dysgeusia, vasodilation, dry mouth, and feeling cold. Most adverse events occurred within 5 minutes of the contrast being administered, and resolved spontaneously in 15 minutes.
- The most common adverse events of prostanoids were headache, facial flushing, nausea, vomiting, and diarrhea.
- Possibility of false positive and false negative results with screening/diagnostic tests.

Contraindications

Contraindications

- Mechanical, non-selective debridement is contraindicated in arterial wounds.
- In cases of severe ischemia, debridement may be contraindicated.
- Do not debride wounds with stable, black eschars until perfusion status is determined: debridement may be contraindicated.
- Hydrocolloids are contraindicated in infected wounds.
- Antiembolism compression stockings (AECS) are considered contraindicated in patients who have lower-extremity arterial disease (LEAD), neuropathy, edema and/or wounds on the heel/foot, ankle or leg due to some case reports of tissue damage or necrosis associated with the use of AECS.
- Magnetic resonance angiography (MRA) cannot be used on patients with pacemakers, defibrillators, metallic stents, clips or coils.
- Some manufacturers indicate that LEAD is a contraindication for their deep vein thrombosis (DVT) prophylaxis device.
- Computed tomographic angiography (CTA) due to use of an iodinated contrast agent should not be used in patients with renal disease.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Mobile Device Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Wound, Ostomy and Continence Nurses Society (WOCN). Guideline for management of wounds in patients with lower-extremity arterial disease. Mount Laurel (NJ): Wound, Ostomy and Continence Nurses Society (WOCN); 2014. 204 p. (WOCN clinical practice guideline series; no. 1). [625 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2002 Jun (revised 2014)

Guideline Developer(s)

Wound, Ostomy and Continence Nurses Society - Professional Association

Source(s) of Funding

No funding source has been identified.

Guideline Committee

Wound, Ostomy and Continence Nurses Society (WOCN) Lower-Extremity Arterial Disease Wound Guidelines Task Force

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Financial Disclosures/Conflicts of Interest

Individuals involved in developing clinical practice guidelines are charged by the Wound, Ostomy and Continence Nurses Society (WOCN) to develop objective, comprehensive and practical guidelines. To ensure the integrity of the WOCN Society and the Clinical Practice Guideline Program, prior to participating in any guideline activity, participants submit a Disclosure Form to the WOCN Society. On the Disclosure Form, task force members are asked to identify any financial relationships with commercial companies that would create a conflict such as when the company's products or services are related to the subject of the guideline. All members of the guideline task force have submitted a Disclosure Form, which was reviewed by the WOCN Society's executive vice president, who determined that no conflict of interest exists with any individual task force member.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Bonham PA, Flemister BG. Guideline for management of wounds in patients with lower-extremity arterial disease. Mount Laurel (NJ): Wound, Ostomy and Continence Nurses Society (WOCN); 2008. 63 p. (WOCN clinical practice guideline series; no. 1). [268 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Not available at this time.

Print copies: Available for purchase for a nominal fee from the Wound, Ostomy and Continence Nurses Society (WOCN), 1120 Rt. 73, Suite 200, Mt. Laurel, NJ, 08054; Web site: www.wocn.org. Orders can be placed through the WOCN Society's Online Bookstore.

Availability of Companion Documents

The following are available:

- LEAD with the right notes: get in tune with the updated 2014 WOCN LEAD guidelines. Continuing education course. Available for purchase from the Wound, Ostomy and Continence Nurses Society (WOCN) Continuing Education Center Web site .
- The WOCN Society's Evidence-Based Wound Care Guidelines and Fecal Ostomy Best Practice Mobile App is available for purchase via iTunes or Google Play. More information on the Mobile App is available on the WOCN Society's Mobile App Web page .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on December 13, 2002. The information was verified by the guideline developer on January 13, 2003. This summary was updated by ECRI Institute on July 25, 2008. The updated information was verified by the guideline developer on August 5, 2008. This summary was updated by ECRI Institute on January 5, 2010 following the U.S. Food and Drug Administration advisory on Plavix (Clopidogrel). This summary was updated by ECRI Institute on May 17, 2010 following the U.S. Food and Drug Administration advisory on Plavix (clopidogrel). This summary was updated by ECRI Institute on June 27, 2011 following the U.S. Food and Drug Administration advisory on Zocor (simvastatin). This summary was updated by ECRI Institute on April 13, 2012 following the U.S. Food and Drug Administration advisories on Statin Drugs and Statins and HIV or Hepatitis C drugs. This summary was updated by ECRI Institute on July 8, 2015. The updated information was verified by the guideline developer on August 28, 2015.

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